



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2015-N-0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of a New Animal Drug Application; Penicillin G Procaine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) providing for the use of penicillin G procaine in medicated feed of poultry and swine. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of NADA 046-666 that provides for use of Type A medicated articles containing penicillin G procaine to manufacture medicated feeds administered

to poultry and swine. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed. Note this NADA was identified as being affected by guidance for industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209," December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 Notice of withdrawal of approval of application, notice is given that approval of NADA 046-666, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: October 6, 2015.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2015-25919 Filed: 10/9/2015 08:45 am; Publication Date: 10/13/2015]